

### REMARKS/ARGUMENTS

Claims 17, 19-47 and 49-57 are under examination in the application. The Office Action mailed on September 18, 2008, includes the following objections and rejections:

1. Claims 17, 23-25, 34-44 and 46-47 are rejected under 35 U.S.C. 102(b).
2. Claims 17, 19-47, 49-52 are rejected under 35 U.S.C. 103(a).
3. Claims 53-57 are rejected under 35 U.S.C. 103(a).
4. Claims 17, 19-47 and 49-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting.

#### *Claims 17, 23-25, 34-44 and 46-47 are rejected under 35 U.S.C. 102(b)*

Claims 17, 23-25, 34-44 and 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Garzia (US 3,697,563, hereafter referred to as "Garzia"). Applicants assert that Garzia fails to anticipate the present invention.

Garzia does not identically disclose every element of the claimed invention. See *Corning Glass Works v. Sumitomo Electric*, 9 USPQ 2d 1962, 1965 (Fed. Cir. 1989). A reference that excludes a claimed element, no matter how insubstantial or obvious, is enough to negate anticipation. *Connell v. Sears, Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983).

Garzia fails to disclose a method for treating a patient in need of treatment for a cardiac disorder, by administering to said patient an effective amount of a **n-heptanoic acid** composition to provide relief to said patient from said cardiac disorder selected from cardiac muscle weakness or cardiac myopathy. Garzia may disclose (3,4,5-Trimethoxy-benzamido)-alkanoic acids but that is not **n-heptanoic acid**. Therefore, Garzia does not identically disclose the instant invention. In addition, of the compounds that are made by Garzia it is clearly stated in column 2, lines 16-18 that, "[t]he caproic acid derivative is preferred." Garzia discloses that in his system an even carbon chain molecule is preferred. Clearly, teaching against the instant invention.

Garzia fails to meet the standard of teaching identically the instant invention. As a result Garzia CANNOT anticipate the instant invention. Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 102(b).

***Claims 17, 19-47, 49-52 are rejected under 35 U.S.C. 103(a)***

Claims 17, 19-47, 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garzia, in view of Jandacek et al., (US 4,753,963, hereafter referred to as "Jandacek") and Jones, et al. (British Med. J. 1961, 1276-1278, hereafter referred to as "Jones"). Applicants respectfully submit that claims 17, 19-47, 49-52 are not obvious over the cited art and are, therefore, allowable under 35 U.S.C. § 103(a) for the reasons stated below.

To establish a *prima facie* case of obviousness there must be: (1) some suggestion or motivation either in the reference itself, or within the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) a reasonable expectation of success, and (3) a teaching or suggestion in the prior art reference of all of the claim limitations (MPEP § 2143). *In re Vacek*, 947 F. 2d. 488 (Fed. Cir. 1991). The combination of Garzia and Jandacek and Jones fails on all counts to establish a *prima facie* case of obviousness.

First the combination fails to teach all of the claim limitations. Garzia, discussed *supra* and arguments incorporate herein by reference, does not disclose a method for treating a patient in need of treatment for a cardiac disorder, by administering to said patient an effective amount of a **n-heptanoic acid** composition to provide relief to said patient from said cardiac disorder selected from cardiac muscle weakness or cardiac myopathy. Garzia may disclose (3,4,5-Trimethoxy-benzamido)-alkanoic acids. Garzia discloses that in his system an even carbon chain molecule is preferred.

The addition of Jandacek does not cure these deficiencies, and merely teaches a nutritional fat particularly suitable for enteral and parenteral products. The combination still does not teach a method for treating a patient in need of treatment for a cardiac disorder, by

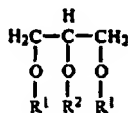
administering to said patient an effective amount of a **n-heptanoic acid** composition to provide relief to said patient from said cardiac disorder selected from cardiac muscle weakness or cardiac myopathy. Although Jandacek may disclose a nutritional fat suitable for enteral and parenteral products it does not disclose a triheptanoin composition.

Even if Jandacek did disclose an odd carbon fatty acid of seven or less carbons (which it does not), it would not anticipate the present invention because Jandacek does not enable one skilled in the art to practice the claimed invention, and does not place the allegedly disclosed matter in the possession of the public.

Further, to anticipate a claim, "a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996). As stated by the Courts in Akzo N.V. v. ITC, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986) and Titanium Metals Corp. v. Banner, 227 U.S.P.Q. 773, 778 (Fed. Cir. 1985), the anticipating prior art reference "must enable one skilled in the art to practice the claimed invention", thus placing the allegedly disclosed matter in the possession of the public." (emphasis added)

The mere broad listing of different compounds by Jandacek does not place a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof in possession of the public. Jandacek provides nothing more than a laundry list of possible triglyceride compounds. Jandacek discloses a list of R groups that are a part of the triglyceride that includes n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, and n-undecanoyl, lauroyl, myristoyl, palmitoyl, stearoyl, oleoyl, linoleoyl, linolenyl groups; however, no indication as to which R groups may be used with another R group and which combinations may be used. Jandacek merely teaches a laundry list of compounds that can be present at the particular R group but provides no indication of which R group combinations are operable.

The present application relates to nutritional fats particularly suitable for enteral and parenteral products. These fats consist essentially of from about 50 to 100% by weight triglycerides of the following formula:



wherein each R<sup>1</sup> group is selected from n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, and n-undecanoyl groups; and the R<sup>2</sup> groups comprise from 0 to about 90% saturated acyl groups selected from n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, n-undecanoyl, lauroyl, myristoyl, palmitoyl, stearoyl and mixtures thereof; from 0 to about 90% oleoyl groups; from about 10 to 100% linoleoyl groups; and from 0 to about 10% linolenoyl groups.

Jandacek is not enabling and its mere broad listing of possible different compounds does not place seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof in possession of the public. See additionally, *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 586 F. Supp. 1176, 1221, 222 USPQ 863 (D. Kan. 1984). *af'd in part & rev'd in pan*, 772 F.2d 1570, 227 USPQ 177 (Fed. Cir. 1985) ("a printed publication which merely names a new compound or substance is insufficient as an anticipation.") (emphasis added); *Air Products & Chem., Inc. v. Chas. S. Tanner Co.*, 219 USPQ 223 (D. S.C. 1983) ("a prior art reference which contains a broad general disclosure requiring guessing, testing, speculation or 'picking and choosing' from an encyclopedic disclosure will not anticipate.") (emphasis added). The only examples, presented by Jandacek are triglyceride with 3 even numbered carbon chains attached. Specifically, an 18 carbon chain and two 8 carbon chains attached to a glycerol, see Column 4, lines 12-13 of Jandacek below:

The synthesis of 2-linoleoyl-1,3-dioctanoin according to the present invention is described as follows:

The examples in Jandacek are triglyceride, i.e., glycerol that is esterified with three even chain fatty acids, i.e., a 18 carbon chain and two 8 carbon chains, see above. Jandacek does not teach/enable a triglyceride with an odd carbon fatty acid of seven or less carbons.

Furthermore, Jandacek does not enable heptanoates, heptanoyl or how to make and use any odd carbon chain fatty acids. Jandacek does not disclose a source for odd chain fatty acids

(e.g., n-heptanoyl), although other sources are discussed, e.g., "Particularly preferred vegetable oils for forming these fatty acid mixtures include soybean oil, corn oil, sunflower oil, safflower oil, and mixtures thereof" Column 4, lines 3-6 of Jandacek. Jandacek provides no guidance to: making seven carbon fatty acid compositions selected from triheptanoin or n-heptanoic acid or derivatives thereof; how to purify a seven carbon fatty acid compositions selected from triheptanoin or n-heptanoic acid or derivatives thereof; how much of the seven carbon fatty acid compositions to administer to an infant or any other specific teaching the a seven carbon fatty acid compositions selected from triheptanoin or n-heptanoic acid or derivatives thereof. Jandacek does not disclose how to isolate, purify, characterize or identify the odd chain fatty acids (e.g., n-heptanoyl). The combination fails to teach a method for treating a patient in need of treatment for a cardiac disorder by providing a patient in need of treatment for a cardiac disorder; and administering to said patient an effective amount of a n-heptanoic acid composition to provide relief to said patient from said cardiac disorder selected from cardiac muscle weakness or cardiac myopathy.

The addition of Jones does not cure these deficiencies. The Office Action adds Jones to show fat mal-absorption in congestive heart failure.

Jones et al. is added to show fat mal-absorption in congestive heart failure, thus, motivating one of ordinary skill in the art to administer the formulation of Jandacek et al to patients with fat malabsorption because Jones et al. teach that fat malabsorption are found in patients with congestive heart failures. See entire doc. of Jones et al.

Fat mal-absorption is the state arising from abnormality in digestion or absorption of food nutrients across the gastrointestinal (GI) tract. Impairment can be of single or multiple nutrients depending on the abnormality. This may lead to malnutrition and variety of anaemias. Jones teaches that fat mal-absorption in congestive heart failure leads to steatorrhoea, which is a condition characterised by an increase in fat content in stools leading to the production of pale, bulky, offensive and loose stools. Along with anaemia, steatorrhoea is one of the primary clinical features of malabsorption syndromes. Jones teaches that the fat is not absorbed in

subjects but excreted in the stool. Therefore, the skilled artisan reading Jones would come to the conclusion that if fats were not absorbed but rather excreted in the stool it would be of little benefit to provide a fat supplement or a diet including fats. There would be no likelihood of success or motivation to combine since the fatty acid composition would not be adsorbed but excreted without providing any nutritional benefit. As a result, Jones teaches away from the instant invention.

Therefore, the combination fails to teach to all of the claim limitations of the instant invention. In addition, the combination fails to provide suggestion to modify the reference and fails to provide a reasonable expectation of success. The Office Action states

One of ordinary skill in the art would have been motivated to substitute the compound formulation with  $\xi$ (3,4,5- trimethoxybenamido)-heptanoic acid in Garzia to the formulation of Jandacek (see supra) and employ in the treatment of cardiac disorders because the Jones reference teaches that fat malabsorption is found in patients with cardiac disorders and thus any cardiac disorder results in cardiac muscle weakness. One of ordinary skill in the art would have expected success in employing the formulation of Jandacek to treat cardiac disorders. With regards to the doses as

First, the combination fails to teach the specific compositions of the instant invention. Garzia teaches (3,4,5-Trimethoxy-benzamido)-alkanoic acids. There is no expectation of success or motive to combine since Jones teaches that fat malabsorption is found in patients with cardiac disorders (i.e., they cannot metabolize fat).

Accordingly, Applicants respectfully submit that claims are not obvious over the combination of Garzia and Jandacek and Jones are, therefore, allowable under 35 U.S.C. § 103(a). Applicants respectfully request that the rejection of claim be withdrawn.

***Claims 53-57 are rejected under 35 U.S.C. 103(a)***

Claims 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garzia in view of Jandacek, and Jones and further in view of Niezen-Koning J. Inher. Metab. Dis 18, 1995,230-232, hereafter referred to as "Niezen-Koning" and Bach et al. Am. J. Clin. Nutri. 1982; 950-962, hereafter referred to as "Bach". Applicants respectfully submit that claims 53-57 are not obvious over the cited art and are, therefore, allowable under 35 U.S.C. § 103(a) for the reasons stated below.

To establish a *prima facie* case of obviousness there must be: (1) some suggestion or motivation either in the reference itself, or within the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) a reasonable expectation of success, and (3) a teaching or suggestion in the prior art reference of all of the claim limitations (MPEP § 2143). *In re Vacek*, 947 F. 2d. 488 (Fed. Cir. 1991). The combination of Garzia and Jandacek and Jones and Niezen-Koning and Bach fails on all counts to establish a *prima facie* case of obviousness.

For the reasons stated above and incorporated herein, the combination of Garzia and Jandacek and Jones fails to establish a *prima facie* case of obviousness. The addition of Niezen-Koning and Bach do not cure these deficiencies. Specifically, the disclosure of disorders that affect the transport of long-chain fatty acids by Niezen-Koning and the even chain fatty acids of Bach still fail to disclose a method for treating a patient in need of treatment for a cardiac disorder, by administering to said patient an effective amount of a **n-heptanoic acid** composition to provide relief to said patient from said cardiac disorder selected from cardiac muscle weakness or cardiac myopathy.

Accordingly, Applicants respectfully submit that claims are not obvious over the combination of Garzia and Jandacek and Jones and Niezen-Koning and Bach are, therefore, allowable under 35 U.S.C. § 103(a). Applicants respectfully request that the rejection of claim be withdrawn.

***Claims 17, 19-47 and 49-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable***

The Examiner states the subject matter claimed in the instant application is disclosed in the Patent Application Number 10/371,385 and is claiming common subject matter with the instant application. Applicants assert that a terminal disclaimer in compliance with 37 CFR 1.321(c) will be filed upon notice of allowable claims in either application to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting patent applications are shown to be commonly owned with this application. See 37 CFR 1.130(b).

***Claims 17, 19-47 and 49-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting***

The Examiner states the subject matter claimed in the instant application is disclosed in the Patent Application Number 10/748,432 and is claiming common subject matter with the instant application. Applicants assert that a terminal disclaimer in compliance with 37 CFR 1.321(c) will be filed upon notice of allowable claims in either application to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting patent applications are shown to be commonly owned with this application. See 37 CFR 1.130(b).



Appl. No. 10/748,495  
Response dated: Oct. 31, 2008  
Reply to Office Action of Sept. 18, 2008

**Conclusion**

In light of the remarks and arguments presented above, Applicants respectfully submit that the claims in the Application are in condition for allowance. Favorable consideration and allowance of the pending claims 17, 19-47 and 49-57 are therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: October 31, 2008.

Respectfully submitted,



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